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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/663,618	06/14/1996	PATRICK W. GRAY	27866/32960	9362

7590 12/16/2004

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

08/663,618

Applicant(s)

GRAY, PATRICK W.

Examiner

Rebecca E. Prouty

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 November 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1-12.Claim(s) objected to: none.Claim(s) rejected: 13-18 and 32.Claim(s) withdrawn from consideration: none.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Art Unit: 1652

The rejection of Claims 13-18 and 32 under 35 U.S.C. 112, second paragraph due to the indefiniteness of the term "stringent conditions" is maintained. Applicants argue that the last paragraph of page 4 of the specification provides exemplary stringent hybridization conditions. It also explains that those of skill in the art understand that variation based on the individual situation occurs, but that formulas standard in the art are appropriate for determining the exact conditions. Thus, using the specification as a guide along with his knowledge and experience, one of ordinary skill in the art would understand the meaning of "stringent conditions" under any individual condition. This is not persuasive because merely because a skilled artisan would consider a single set of conditions (such as the exemplary conditions recited by the specification) to be within the scope of the term does not mean that they can define the metes and bounds of the term. As previously stated the scope of the term stringent is highly vague in the art and varies from artisan to artisan. The only reference to what this term means within the instant claims is the specification itself. It merely provides an example of what must be included but does not define the boundaries of the term. For example the conditions recited in the specification are hybridization at 42°C in 50% formamide and washing at 60°C in 0.1X SSC, 0.1% SDS. Would conditions in which the temperature was lowered to room temperature, or the amount of formamide was reduced still be

Art Unit: 1652

within the term "stringent"? Each of these situations would not be considered equivalent to the exemplary conditions but would likely be within at least most artisans definition of "low stringency conditions".

The rejection of Claim 32 under 35 U.S.C. 112, second paragraph due to the indefiniteness of the term "immunogenic fragment" is also maintained. Applicants argue that in light of the specification (see page 6, lines 3-4, and 23-25), one of ordinary skill in the art would understand the term to mean a fragment that will induce an antibody to the human chitinase of SEQ ID NO:2. However this is not persuasive because it is not clear that "chitinase" within the phrase "specifically reactive with chitinase" refers only to SEQ ID NO:2. Furthermore this does not define the conditions under which "specificity" must be exhibited.

The rejection of Claim 32 under 35 U.S.C. 112, first paragraph for lacking a sufficient written description is also maintained. Applicants argue that the claim is defined in both structure and function. However giving the phrase "immunogenic fragment" its broadest reasonable interpretation, the claimed genus is still highly diverse with regards to structural and functional characteristics such that the two disclosed species cannot be considered to be representative of the genus. The claimed genus of polynucleotides includes fragments with use only as probes and/or primers, fragments which could be used to


Art Unit: 1652

produced peptides with use in assaying and/or purifying human chitinase, and fragments which could be used to produce proteins with chitinase activity. The two disclosed species could be considered to be representative only of those polynucleotides which encode enzymatically active fragments of the human chitinase of SEQ ID NO:2. As such the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Rebecca Prouty
Primary Examiner
Art Unit 1652